REMARKS/ARGUMENTS

Claims 10-13, 17-19, 22-23 and 32-33 are pending. The claims have been amended. The specification has been amended. No new matter has been introduced. Reexamination and reconsideration of the present application is respectfully requested.

Specification

In the specification, one paragraph has been amended to include information regarding the biological deposit.

Claim Rejections

Claims 10-13, 17-19, 22-23 and 32-33 are pending. Claims 1-10, 14-16, 20-21 and 24-31 have been canceled pursuant to a Restriction Requirement. The Applicant reserves the right to later file one or more divisional applications directed to the subject matter of the non-elected/cancelled claims.

35 U.S.C. §112, second paragraph

The Examiner rejected to the claims 17, 19, 22 and 32-33 for indefiniteness under 35 U.S.C. 112, second paragraph. The Examiner states that "it cannot be determined whether applicant intends stringent or non-stringent conditions." Applicants respectfully traverse this rejection.

The claims do not recite the term "hybridization." As such, the grounds for rejection based upon an absence of reciting hybridization conditions (for example, stringent or non-stringent) are inapplicable and, therefore, improper. Furthermore, what is disclosed in the specification is well within the capabilities of one of skill in the art to make and use the invention as claimed. The specification discloses how the probes are developed and the condition parameters under which hybridization occurs. Page 25, Example 6. For example, the specification states "To achieve the same stringency during the washing step, as in the hybridization step, the wash solution contained 20mM Tris/HCl (pH 7.4), 0.01% SDS, 5 mM

EDTA, and NaCl. The concentration of NaCl varied according to the percent formamide used in the solution. For 20% formamide the NaCl concentration was 215 mM, for 30% it was 120 mM, and for 40% the NaCl concentration was 46 mM...The optimum stringency was determined to be 30% formamide for the S-G-Nsspa-0149-a-A-18 probe. For the S-G-Nsspa-0149-a-A-19 probe the optimum stringency was determined to be 20% formamide. The optimum stringency was determined to be 20% formamide for the probe represented by SEQ ID NO:21, and 20% formamide for the probe represented by SEQ ID NO:24." Page 27, lines 8-20 to Page 28, lines 1-3. In addition, there are a number of well-known methods and techniques in the art that are available for use in identifying the variants. These methods and techniques are routinely practiced in the art (*e.g.*, alignment search tool (BLAST) (S.F. Altschul et al. 1990. Basic local alignment tool. J. Mol. Biol. 215:403-410) and CHECK_PROBE (B.L. Maidak et al. 1994. The ribosomal database project. Nucleic Acids Res. 22:3485-3487.)).

Thus, even though the claims are not claiming a method for detecting the variants, the specification nonetheless provides more than sufficient disclosure by showing one of skill in the art how to obtain the probes, test bacterial DNA, and isolate and identify the claimed variants. In fact there are many patents that have been allowed in which disclosure of exemplary hybridization condition parameters was found sufficient for enabling similar claims, although there is no recitation of hybridization conditions in the claim language. For example, see U.S. Patent No. 6,905,864 (*Primary Examiner:* Marx; Irene) and U.S. Patent No. 6,825,002 (*Primary Examiner:* Marx; Irene).

As such, the Applicants respectfully submit that the claims comply with the requirements of 35 U.S.C. 112.

35 U.S.C. §112, first paragraph

The Examiner rejected to the claims 10-13, 17-19, 22-23 and 32-33 under 35 U.S.C. 112, first paragraph because "[i]t is not clear if the written description is sufficiently repeatable to avoid the need for a deposit." The Applicant provides herein a declaration identifying a deposit of the relevant biological material as suggested by the Examiner. The Applicant also provides herein documentation from the depository confirming the deposit. Finally, the specification has

been amended to include the information regarding the deposit.

The Applicant respectfully submits that the above rejection has been overcome.

35 U.S.C. §112, first paragraph

The Examiner rejected to the claims 17, 19, 22 and 32-33 for non-enablement under 35 U.S.C. 112, first paragraph.

The Examiner rejects claims based upon the written description requirement of patentability. It is alleged that the claims encompass a large variable genus but that the specification only provides the sequence of SEQ ID NO:18. Thus, the Examiner concludes that one of ordinary skill in the art would not recognize Applicants as having possession of the claimed invention. Applicants respectfully traverse this rejection.

The presented claims encompass bacterial strains comprising specific nucleotide sequences based upon their ammonia-oxidizing functions. Those strains must further have an amino acid sequence at least 96% identical to SEQ ID NO:18. The claims are thus not directed to an unrestricted amount of sequences based solely upon one factor, such as function. For example, a claim solely directed to a nucleotide sequence encoding a protein with the activity of ammonia-oxidation would not be valid. The present claims have both structural and functional limitations. While some of the compounds having 96% homology might not be operative, *i.e.*, they might not be able to oxidize ammonia. However, in order to eliminate the inoperative embodiments, Applicants have coupled the requirement for maintaining a high degree of homology with the functional requirement that oxidation of ammonia must be maintained.

Structurally, the claims are limited to nucleotide sequences that are either identical in sequence to SEQ ID NO:18 or which are at least 96% homologous. Even though the claims therefore encompass a large number of specific sequences, the disclosure teaches one of skill in the art in screening for the required homology and testing for the claimed function (see for example, Examples 1-16). Thus, the homology requirement and functional requirement limit the number of compounds to a defined group, *i.e.*, the claims are not open-ended. *Enzo Biochem,*

Inc. v. Gen-Probe Inc., 323 F.3d 956, 964 (Fed. Cir. 2002)(citing *Regents of the University of California v. Eli Lilly & Co.* 119 F.3d 1559 (Fed. Cir. 1997): According to the PTO, *Lilly* requires the disclosure of "detailed, relevant identifying characteristics ... i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics," and the Federal Circuit has adopted this interpretation.). Even though it would be impractical, one of ordinary skill in the art could, in principle, identify and write down every compound claimed. Thus, conceptually, Applicants were clearly in possession of the claimed invention at the time of filing.

In light of the above considerations, Applicants respectfully submit that the present claims meet the written description requirement of patentability. It is therefore respectfully requested that the Examiner's rejection based upon the written description requirement of patentability be withdrawn.

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Conclusion

This response is being submitted within the three month deadline. In the case any fee is owed, please charge deposit account number 03-3975 (ref. 81289-284779). The Applicant believes that claims 10-13, 17-19, 22-23 and 32-33 are now in condition for allowance, and a favorable action is respectfully requested. If, for any reason, the Examiner finds the application other than in condition for allowance, the Examiner is requested to call the undersigned attorney at the Los Angeles telephone number (213) 488-7100 to discuss the steps necessary for placing the application in condition for allowance should the Examiner believe that such a telephone conference would advance prosecution of the application.

Respectfully submitted,

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